The opinion in support of the decision being entered today is not binding precedent of the Board

Paper 104

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

PHILLIP A. FURMAN
and GEORGE R. PAINTER, III

Junior Party,
(Application 07/775,187)

v.

BERNARD BELLEAU, DECEASED,
BY PIERRETTE BELLEAU,
and NGHE NGUYEN-BA

Senior Party,
(Patent 5,532,246 and Reissue Application 09/585,431)

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PAT & T.M. OFFICE
BOARD OF PATENT APPEALS
AND INTERFERENCES

Patent Interference No. 104,524

Before: TORCZON, LANE, and TIERNEY, Administrative Patent Judges.

LANE, Administrative Patent Judge.

DECISION ON PRIORITY

I. Introduction

Because of their similar subject matter and common parties, a judgment consolidating interferences 104,396, 104,523("'523 ") and 104,524 ("'524 ") was entered (104,396 at Paper 30, '523 and '524 at Paper 2). Judgment awarding priority against Cheng as to both counts in interference 104,396 was entered on 3 May 2002 (Paper 233 at 78).

Oral hearing on priority was held in interferences '523 and '524 on 6 May 2002. In interference '523 we award priority against Furman as to the single count. In interference '524 we award priority against Furman as to all counts.

Brief summary of the involved technology

The interference is directed to a method of administering an effective amount of an enantiomeric compound for the treatment of hepatitis B virus ("HBV"). The enantiomeric compound of interest is cis-4-amino-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1H)-pyrimidin-2-one which can be in the form of its (-) enantiomer or its (+) enantiomer. When both the (-) and (+) enantiomers are present in equal amounts, the mixture is referred to as a "racemic mixture," which in this instance is also known as "BCH-189." (Belleau et al., U.S. Patent No. 5,532,246, col. 2, lines 33-42). The enantiomers of BCH-189 are referred to as the (+) and (-) optical isomers because they cause the plane of polarized light to rotate in opposite directions. The (+) enantiomer rotates light in a polarimeter in a clockwise rotation (dextrorotatory) whereas the (-) enantiomer rotates light in a counterclockwise direction ("levorotatory").

Brief summary of the facts[1]

Burroughs Wellcome, Inc. ("BW")[2] first received a sample of BCH-189 from BioChem Pharma[3] in 1989. BW tested the BCH-189 and found it to be active against human immunodeficiency virus ("HIV"). Thereafter, Dr. Dennis Liotta of Emory University sent a group of nucleoside analogs synthesized by Dr. Liotta ("the Liotta samples") to BW for anti-viral testing. Among the Liotta samples was BCH-189. In late October and early December of 1990, BW consultant Dr. Brent Korba tested BCH-189 for its activity against HBV. In mid December of 1990, Dr. Korba provided a report indicating that BCH-189 was active against HBV. BW did not test the separate enantiomers of BCH-189 for anti-HBV activity until July of 1991.

Brief summary of the decision

Since Furman has failed to show that it was the first to invent the subject matter of any of the counts in the interference by a preponderance of the evidence, we enter judgment against Furman as to all counts. In particular, we determine that Furman has not shown by a preponderance of the evidence: (1) that Furman actually reduced to practice the invention defined by count 1, count 2, or count 3 prior to Belleau's priority benefit date of 3 January 1991; or (2) that Furman was diligent up to Furman's constructive reduction to practice date of 2 May 1991.

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[1] It is our understanding that these facts are not in dispute (Paper 88 at 6,7,11, and 12 and Paper 91 at 1).

[2] We understand Burroughs Wellcome, Inc. to refer to Furman's real party in interest. (See *infra* at finding of fact ("FF") 5).

[3] Belleau has identified BioChem Pharma as its real party in interest.

II. Findings of Fact

The interference

1. The interference was declared on 14 April 2000 between Belleau's patent 5,532,246 ("'246") and Furman's application 07/775,187 ("'187").

2. We granted Belleau's preliminary motion to add its reissue application 09/585,431, filed 2 June 2002, to the interference (Paper 65 at 18).

3. According to Belleau, Biochem Pharma, Inc. is its real party in interest in the involved Belleau '246 patent while Glaxo Wellcome is said to have licensing rights in the involved Belleau patent (Paper 4).

4. Unrecorded agreements are said to exist between Tanaud International, a wholly owned subsidiary of Biochem Pharma, and Biochem Pharma by which Tanaud possesses formal legal title to the '246 patent. Under these agreements, Biochem Pharma is said to have the right to maintain the '246 patent in its name (Paper 4).

5. According to Furman, its real party in interest is Glaxo Wellcome, Inc. (Paper 9). It is our understanding that it is appropriate to consider Burroughs Wellcome, Inc. to be the same as Glaxo Wellcome, Inc., at least for purposes of this decision.

The counts

6. The interference was declared with the following count, count 1, as the sole count in the interference (Paper 1 at 47):

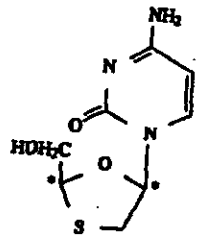
A method according to claim 1 of Belleau patent 5,532,246

or

a method according to claims 1, 2, 3, or 5 of Furman application 07/775,187.

7. Belleau claim 1 reads as follows:

> 1. A method for the treatment of a mammal, including a human[4], suffering from hepatitis B infection, comprising administration of an effective amount of a compound of formula (I)



(I)

> or a pharmaceutically acceptable salt, ester, or salt of an ester thereof to said mammal.

8. Furman claims 1, 2, 3, and 5 read as follows:

> 1. A method of interfering with HBV production in [a] HBV infected host comprising the administration of an effective HBV production interfering amount of the compound

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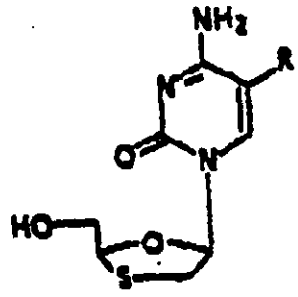
4 The phrase "including a human" is superfluous since "mammal" includes human.



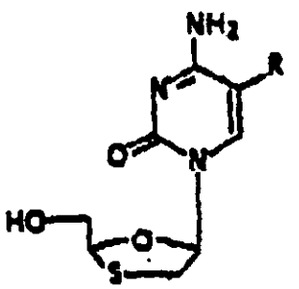
(I)

wherein R is hydrogen for C_{1-3} alkyl or a pharmaceutically acceptable salt, ester or other physiologically functional derivative thereof to said HBV infected host.

2. A method of interfering with the HBV production in an HBV infected host comprising the administration of an effective HBV production interfering amount of the compound 1-(2-(hydroxymethyl)-1,3-oxathiolan-5-yl)cytosine to said HBV infected host.

3. A method of interfering with HBV production in a HBV infected host comprising the administration of an effective HBV production interfering amount of the compound 1-(2-hydroxymethyl)-1,3-oxathiolan-5-yl)-5-methylcytosine to said HBV infected host.

5. A method of treating an HBV infected host comprising the administration of an effective HBV treatment amount of the compound



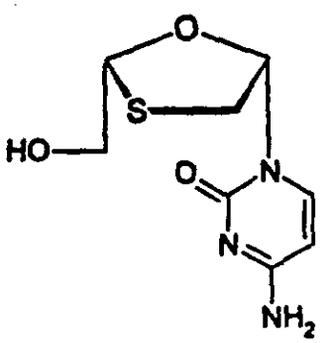
(I)

wherein R is hydrogen or C_{1-3} alkyl or a pharmaceutically acceptable salt thereof to said HBV infected host.

9. In our decision on preliminary motions (Paper 65), we provisionally granted Belleau's preliminary motion to add count 2 (preliminary motion 1) and Belleau's preliminary motion to add count 3 (preliminary motion 16) to the interference (Paper 65 at 20).

10. Count 2 reads as follows:

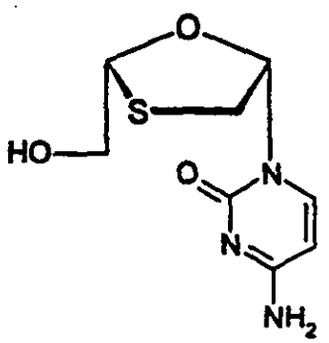
A method of treating hepatitis B virus infection and/or inhibiting hepatitis B virus replication in a patient in need thereof, including humans and other mammals, comprising administering to said patient an effective amount of (-)-cis-4-amino-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1H)-pyrimidin-2-one of the formula:



which is substantially free of the corresponding (+)-enantiomer or contains more of said (-)-enantiomer than the corresponding (+)-enantiomer, or a pharmaceutically acceptable salt, ester or salt of an ester thereof.

11. Count 3 reads as follows:

A method of treating hepatitis B virus infection and/or inhibiting hepatitis B virus replication in a patient in need thereof, including humans and other mammals, comprising administering to said patient an effective amount of (-)-cis-4-amino-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1H)-pyrimidin-2-one of the formula:



which is substantially free of the corresponding (+)-enantiomer, or a pharmaceutically acceptable salt, ester or salt of an ester thereof.

Redeclaration

12. Based on our decision on preliminary motions, the interference was redeclared provisionally adding count 2 and count 3 (Paper 66).

13. In the redeclaration the following claims were designated as corresponding to count 1:

Furman: 1-3 and 5

Belleau '246: 1-3 and 6-9

Belleau '431: 1-3 and 6-10, 12, and 14

and the following claims were designated as corresponding to count 2 and count 3:

Furman: 4

Belleau '246: 4-9

Belleau '431: 4-9, 11, 13, and 15

14. In the redeclaration, Furman was accorded priority benefit of United Kingdom application 9109506.7, filed 2 May 1991, as to counts 1, 2, and 3.

15. In the redeclaration, Belleau was accorded priority benefit of:

(1) PCT/CA92/00001, filed 3 January 1992;

(2) GB 9109913.5, filed 7 May 1991; and

(3) GB 9100039.8, filed 3 January 1991

as to counts 1, 2, and 3.

16. Neither Furman nor Belleau requests reconsideration of our decision on preliminary motions.

Priority

Furman's preliminary statement:

17. According to Furman's preliminary statement, it conceived and reduced to practice the invention of the counts by 19 July 1990 (Paper 102 and Paper 68).[5]

Furman's inventorship evidence:

18. A conference call was held on 22 January 2002.

19. Thereafter, an Order was entered in the interference (Paper 79). The Order summarized the conference call as follows:

> Party Furman requested the call. During the call, Furman stated it had come into possession of information that may have some relevance to the inventorship of its involved application.

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[5] Furman refiled its original preliminary statement on 2 May 2002 after it could not be located in the record.

> While Furman indicated its belief that the stated inventorship is correct, Furman stated that it believes it has a duty under 37 CFR § 1.56 to disclose the inventorship information. Party Cheng expressed a concern that Furman may be attempting to untimely supplement its priority case through the disclosure of the information. However, party Furman agreed that the inventorship information would be submitted for the limited purpose of complying with its duty of disclosure and not as evidence in its priority case.

20. In the Order it was stated that the inventorship information submitted by Furman could not be relied upon to show priority of invention since it was not timely submitted. (Paper 79 at 3).

21. Belleau did not file a motion to suppress any evidence relied upon by Furman to show priority.

Dr. Furman's testimony:

22. Many of the facts relied upon by Furman to establish priority are based on the declaration testimony of inventor Dr. Phillip A. Furman. (Exh. 2049).

23. Dr. Furman's declaration testimony (Exh. 2049) appears to be among the evidence directed to inventorship that Furman submitted pursuant to the Order (FF 19).

24. In particular, Dr. Furman's testimony indicates that:

(A) He and co-inventor Dr. George R. Painter, III ("the Furman inventors") received a sample of BCH-189 from BioChem Pharma in connection with licensing discussions in 1989. (Exh. 2049 at ¶ 5).

(B) The BCH-189 was tested for anti-HIV activity in 1989 and was found to be very active. (Exh. 2049 at ¶ 5).

(C) From October of 1989 to the end of 1990, Dr. Korba worked as a consultant for BW, developing and operating an anti-HBV testing program. The Furman inventors discussed that they "should test compounds in Dr. Korba's anti-HBV screen that exhibit activity against HIV" because "of similarities in the active sites of the reverse transcriptase enzyme of HIV and the polymerase enzyme of HBV." (Exh. 2049 at ¶¶ 4, 6).

(D) Once it was learned that BCH-189 was active against HIV (in 1989), the Furman inventors discussed sending BCH-189 to Dr. Korba for anti-HBV testing since "the compound could exhibit activity against hepatitis B." (Exh. 2049 at ¶ 7).[6]

(E) In autumn of 1989, the Furman inventors had discussions with Dr. Liotta while attending a virology conference regarding Dr. Liotta's synthesis of nucleoside analogs. (Exh. 2049 at ¶ 8).

(F) The Furman inventors suggested that Dr. Liotta submit any nucleoside analogs he synthesized to BW for testing for antiviral activity. (Exh. 2049 at ¶ 8).

(G) Dr. Furman did not mention the possibility of Dr. Korba's anti-HBV test to Dr. Liotta but did mention BW's "anti-HIV, anti-HSV, and anti-CMV screens".[7] (Exh. 2049 at ¶ 9).

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[6] We have not been directed to evidence indicating that the sample of BCH-189 from BioChem Pharma was ever tested for anti-HBV activity.

[7] We understand HIV to be human immunodeficiency virus, HSV to be herpes simplex virus, and CMV to be cytomegalovirus.

(H) Dr. Furman does not recall Dr. Liotta requesting testing for anti-HBV activity. (Exh. 2049 at ¶ 9).

(I) On 17 or 18 July of 1990, [8] Dr. Liotta sent a group of structurally unidentified compounds marked DCL-01 through DCL-16 ("the Liotta samples") to Dr. Painter. (Exh. 2049 at ¶¶ 11, 12).

(J) The Furman inventors discussed sending the Liotta samples for anti-HBV testing after the compounds had been screened for anti-HIV activity. (Exh. 2049 at ¶ 13).

(K) Thereafter, the Furman inventors learned four of the Liotta samples exhibited anti-HIV activity. (Exh. 2049 at ¶ 15).

(L) In mid-August of 1990, Dr. Liotta identified the Liotta samples and it turned out that one of the samples exhibiting anti-HIV activity was BCH-189. (Exh. 2049 at ¶¶ 16, 17).

(M) Thereafter, the Furman inventors discussed sending the BCH-189 sample to Dr. Korba for anti-HBV testing. (Exh. 2049 at ¶ 16).

(N) At the request of the Furman inventors, BCH-189 was sent to Dr. Korba for anti-HBV testing. (Exh. 2049 at ¶ 21).

(O) Around mid-December of 1990, Dr. Korba provided a report that showed BCH-189 to have anti-HBV activity. (Exh. 2049 at ¶¶ 23, 24).

(P) Dr. Furman was on the distribution list for a memorandum that summarized Dr. Korba's report. (Exh. 2049 at ¶ 24).

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[8] There is a discrepancy between the date Dr. Liotta's letter (Exh. 2039) indicates the samples were received and the date Dr. Painter's notebook (Exh. 2024) indicates the samples were received. Since the one day difference is irrelevant to our decision, we need not and do not attempt to resolve the discrepancy.

25. Furman has not directed us to corroboration for much of Dr. Furman's testimony.

Dr. Liotta's samples:

26. Furman has submitted evidence that appears to be a letter from Dr. Liotta to the Furman inventors. (Exh. 2038).

27. The letter, dated 3 November 1989, states as follows:

> As you know, we have recently developed a number of novel approaches for synthesizing antiviral nucleosides. In the course of our studies, we have prepared a number of novel nucleosides which, to our knowledge, have never been tested for their antiviral activity. It would be very helpful to us if you could evaluate these materials in your antiviral screens. If you are interested in pursuing this matter, would you please arrange to have a testing agreement sent to me so that we can initiate this matter?

28. Furman has submitted evidence that appears to be a letter from Dr. Liotta to Dr. Painter. (Exh. 2039).

29. The letter, dated 18 July 1990, states as follows:

> I was glad to hear that all the legal details between Wellcome and Emory have finally been resolved. As a consequence, I am pleased to be able to send you sixteen samples to be evaluated for antiviral activity. In accord with our conversations on the matter, I have coded the compounds as DCL-01 through DCL-16 (see attached sheet). I look forward to hearing the outcome of the bioassays.

30. Furman has submitted evidence that appears to be a research agreement between BW and Emory University. (Exh. 2040). The agreement states, *inter alia*, that:

The University agrees to prepare and submit novel compounds of suitable purity to Wellcome for antiviral screening and Wellcome agrees to submit results of such antiviral screening to the University.

Dr. Painter's notebook:

31. Furman has submitted evidence including a copy of what appears to be a page of a laboratory notebook. (Exh. 2024).

32. The signature "George R. Painter," dated 17 July 1990, and the witness signature "John P. Shockor ",[9] dated 18 July 1990, appear at the bottom of the notebook page.

33. The notebook page contains notations that:

(A) the sixteen listed compounds, coded DCL-01 through DCL-16, were received from Dr. Liotta for antiviral testing,

(B) the compounds had been sent for HIV testing, and

(C) "Phil Furman and I have discussed sending the compounds (what is left after HIV screen) to Karen Biron HBV test".

34. Furman has submitted evidence that appears to be two pages from Dr. Painter's laboratory notebook. (Exh. 2030).

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[9] While the signature on the notebook page is illegible, we have no reason to discredit Dr. Shockor's declaration testimony that he witnessed the notebook page. (Exh. 2053 at ¶ 6).

35. The signature "George R. Painter," dated 19 August 1990, and the witness signature " John P. Shockor",[10] dated 20 August 1990, appear at the bottom of the notebook page.

36. The notebook page contains notations that appear to identify the sixteen samples that were identified only by code in the 17 or 18 July notebook entry.

37. Notably, DCL-07 is identified as (+) BCH-189, DCL-08 is identified as (-) BCH-189, and DCL-12 is identified as (±) BCH-189.[11]

38. Furman has not presented testimony from Dr. Painter.

Dr. Karen Biron's and Sheila Smith Kondy's[12] testimony:

39. According to Dr. Biron of BW, she initiated contact with Dr. Korba to establish a procedure for anti-HBV testing for BW compounds. (Exh. 2050 at ¶ 3).

40. Karen Biron testified that she would conduct a meeting to discuss "sample priority" since there were a limited number of samples that could be tested by Dr. Korba at any time. (Exh. 2050 at ¶ 4).

41. In her testimony, Dr. Biron refers to a memorandum dated 13 October 1989. (2050 at ¶ 4).

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[10] While the signature on the notebook page is illegible, we have no reason to discredit Dr. Shockor's declaration testimony that he witnessed the notebook page. (Exh. 2053 at ¶ 7).

[11] DCL-07, DCL-08, and DCL-12 are also identified by what is said to be their BW internal codes of 1960U90UA, 1961U90UA, and 1965U90UA, respectively (Paper 88 at 8-9 and Exh. 2012).

[12] It is our understanding that Sheila Smith Kondy and Sheila Smith are the same person.

42. The memorandum states that "[t]here will be a meeting to select the next ten compounds for testing against human HBV by Brent Korba of Georgetown". (Exh. 2018).

43. Neither Dr. Painter nor Dr. Furman is on the distribution list found at the bottom of the memorandum.

44. Ms. Kondy of BW testified that she reported to Dr. Biron and that part of her duties was to collect samples from BW chemists and forward them to Dr. Korba for anti-HBV testing. (Exh. 2052 at ¶¶ 3, 4).

45. According to Ms. Kondy, she sent samples from George Painter to Dr. Korba for anti-HBV testing and recorded the samples in her notebook on 31 October 1990. (Exh. 2052 at ¶ 6).

46. Furman has submitted evidence that is said to be a notebook page from Ms. Kondy's notebook. (Exh. 2011).

47. On the page, under the notation "from G. Painter", is a list consisting of BCH-189 and five other Liotta samples.

48. Of the four Liotta samples said to exhibit anti-HIV activity (Exh. 2045), only BCH-189 appears on the list.

Dr. Korba's test results:

49. According to Furman, Dr. Korba tested BCH-189 in an *in vitro* assay (test) that utilizes a human cell line transfected with HBV DNA (Paper 88 at 10).

50. Furman has submitted evidence that appears to be a report dated

12 December 2000 from Dr. Korba that is said to show that certain tested samples, including BCH-189, exhibited anti-HBV activity. (Exh. 2019).

51. Dr. Biron testified that she received the report from Dr. Korba on 12 December 1990. (Exh. 2050 at ¶ 7).

52. Furman has submitted evidence that appears to be a report dated 14 December 2000 from Dr. Korba that is said to show that certain tested samples, including BCH-189, exhibited anti-HBV activity. (Exh. 2014).

53. Ms. Kondy testified that she received the report from Dr. Korba on 14 December 1990. (Exh. 2052 at ¶ 8).

54. Dr. Biron and Ms. Kondy each testified that she prepared a memorandum reporting the anti-HBV activity of several compounds, including BCH-189. (Exh. 2050 at ¶ 8 and Exh. 2052 at ¶ 8).

55. Furman has submitted evidence that appears to be a memorandum dated 28 December 1990. The memorandum indicates that BCH-189 demonstrated anti-HBV activity in Dr. Korba's test. (Exh. 2015).

56. The Furman inventors are listed on the distribution list for the memorandum. (Exh. 2015).

57. Dr. Furman did not testify that he received or read the memorandum.

58. Ms. Kondy testified that "sometimes" she or Dr. Biron would verbally communicate test results to chemists who submitted compounds for testing. (Exh. 2052 at ¶ 5). However, Ms. Kondy did not testify that either of the Furman inventors submitted BCH-189 for anti-HBV testing or that she verbally

communicated the results summarized in the memorandum (at FF 55) to either of the Furman inventors.

The separate enantiomers of BCH-189:

59. According to Furman, anti-HBV testing of the separate enantiomers of BCH-189 did not begin until July of 1991 (Paper 88 at 13 and 23-24).

III. Discussion

A. The inventorship evidence (i.e., exhibits 2037-2049)

Initially we note that Furman's principal brief on the issue of priority (Paper 85) appears to rely upon evidence that was submitted pursuant to the Order entered 22 January 2002 ("the inventorship evidence") found at Exhibits 2037-2049. For example, Furman relies upon the following evidence ("the inventorship evidence") in its principal brief:

(A) Dr. Furman's testimony (Exh. 2049),

(B) Dr. Liotta's letters (Exhs. 2037 and 2038), and

(C) the agreement between BW and Emory University (Exh. 2040).

It would seem improper for Furman to rely upon the inventorship evidence to establish priority in view of the Order. (FFs 19 and 20).

Belleau did not file a motion to suppress the inventorship evidence. (FF 21). Our consideration of the inventorship evidence does not appear to unfairly prejudice Belleau in the interference, since, even when we consider this evidence, we determine that Furman has not shown that it is prior to Belleau.

B. The counts

The count of an interference is meant to circumscribe the interfering subject matter and thus indicate what evidence is relevant to priority. *Squires v. Corbett*, 560 F.2d 424, 433, 194 USPQ 513, 519 (CCPA 1977). In its preliminary motions, Belleau requested the addition of either count 2 or count 3 on the basis that each of count 2 and count 3 defines an invention that is patentably distinct from the invention defined by count 1.

We noted the following in our decision on preliminary motions (Paper 65 at 10-11):

> The subject matter of Belleau proposed count 2 and proposed count 3 is narrower than that of count 1. The compounds used in the method of count 1 include compounds of the count having any possible ratio of (-) to (+)-enantiomer. The compounds used in the method of Belleau proposed count 2 and proposed count 3 are a subset of the compounds defined by the count where the compounds are either substantially free of the corresponding (+)-enantiomer (Belleau proposed count 2 and proposed count 3) or contain more of said (-)-enantiomer than the corresponding (+)-enantiomer (Belleau proposed count 2).

In our decision on preliminary motions, we *provisionally* granted Belleau's preliminary motion to add count 2 and Belleau's preliminary motion to add count 3, stating the following (Paper 65 at 12-13):

> For reasons that follow, at this time we decline to decide whether Belleau has shown that proposed count 2 or proposed count 3 would not have been obvious over count 1.
>
> The subject matter of Belleau proposed count 2 and proposed count 3 anticipates the subject matter of count 1. If a party proves priority based on subject matter falling within the scope of Belleau proposed count 2 or proposed count 3, then that party also may prevail as to the subject matter of count 1.

> Depending on the priority proofs, it is therefore possible that we will not need to decide if count 1 and Belleau proposed count 2 or proposed count 3 define separately patentable inventions. On the other hand, if one party prevails on priority with respect to count 1 and the opponent prevails on priority with respect to Belleau proposed count 2 or proposed count 3, then we will need to decide if count 1 and Belleau proposed count 2 or proposed count 3 define separately patentable inventions.

On the record before us, Furman has not sufficiently shown that it was prior to Belleau as to the invention defined by either count 1, count 2 or count 3. Accordingly, we need not and do not decide whether count 2 or count 3 define an invention that is separately patentable from the generic invention defined by count 1. For purposes of awarding judgment, we shall award judgment against Furman as to count 1, count 2, and count 3 even though we have not decided whether the invention defined by either of count 2 or count 3 is separately patentable from the invention defined by count 1.

C. Priority

Priority in an interference is awarded to the first party to reduce the invention to practice unless the other party can establish that it was the first to conceive the invention and that it exercised reasonable diligence in later reducing the invention to practice. *Eaton v. Evans*, 204 F.3d 1094, 1097, 53 USPQ2d 1696, 1698 (Fed. Cir. 2000).

A rebuttable presumption exists that, as to each count, the inventors made their invention in the chronological order of their effective filing dates. The burden of proof shall be upon a party who contends otherwise. In an interference between a patent and an application having a filing date on or before the issue date of the patent, the burden of proof to establish priority is by

a preponderance of the evidence. 37 CFR § 1.657(b). This ultimate burden of proof always remains with the junior party in the interference. *Brown v. Barbacid*, 276 F.3d 1327, 1333, 61 USPQ2d 1236, 1239 (Fed. Cir. 2002).

Conception is the formation in the mind of the inventor of a definite and permanent idea of the complete and operative invention, as it is later applied in practice. *Cooper v. Goldfarb*, 154 F.3d 1321, 1327, 47 USPQ2d 1896, 1901 (Fed. Cir. 1998). "An idea is definite and permanent when the inventor has a specific, settled idea, a particular solution to the problem at hand, not just a general goal or research plan he hopes to pursue." *Burroughs Wellcome Co. v. Barr Lab., Inc.*, 40 F.3d 1223, 1228, 32 USPQ2d 1915, 1919 (Fed. Cir. 1994).

A reduction to practice may be either a constructive reduction to practice, which occurs when a patent application is filed, or an actual reduction to practice. *Cooper v. Goldfarb*, 154 F.3d at 1327, 47 USPQ2d at 1901. In order to establish an actual reduction to practice, the inventor must prove that: (1) he constructed an embodiment or performed a process that met all the limitations of the interference count, and (2) he determined that the invention would work for its intended purpose.

Furman relies heavily upon the testimony of Dr. Furman in support of its arguments. In evaluating the credibility of Dr. Furman's testimony, we consider whether that testimony is corroborated. An inventor's testimony used to establish conception or reduction to practice must be corroborated by independent evidence. All pertinent evidence must be evaluated when determining the credibility of an inventor's testimony. For example, under a "rule of reason" analysis, circumstantial evidence of an independent nature may satisfy the corroboration requirement. *Reese v. Hurst v. Wiewiorowski*, 661 F.2d 1222, 1230 , 211 USPQ 936, 940

(CCPA 1981); *Cooper v. Goldfarb*, 154 F.3d at 1330, 47 USPQ2d at 1903. However, the "rule of reason" does not dispense with the requirement for some evidence of independent corroboration." *Coleman v. Dines*, 754 F.2d, 353, 360, 224 USPQ 857, 862 (Fed. Cir. 1985).

Furman argues that it was the first to conceive of and the first to reduce to practice the invention[13] of count 1, count 2 and count 3 ("the counts") (Paper 88 at 17). In particular, Furman argues that:

(1) Furman simultaneously conceived and reduced to practice the invention in July or August of 1990 when:

(a) Dr. Painter recorded receipt of the Liotta samples in his notebook and noted that the samples should be sent for HBV testing after HIV testing (Paper 88 at 17) (FF 33 A-C), or

(b) Dr. Painter recorded the identity of the Liotta samples in his notebook and one of the samples was identified as BCH-189 (Paper 88 at 20). (FF 37).

(2) the July or August reduction to practice was confirmed by 12 December 1990 when Dr. Korba provided his preliminary report on the activity of BCH-189 (Paper 88 at 22). (FF 50).

(3) Furman was diligent in reducing to practice the invention of the counts (Paper 88 at 23).

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[13] We will refer to the invention (singular) of the counts for the sake of simplicity even though we do not decide if the counts are directed to a single patentable invention.

(4) while the testing of BCH-189 (-) enantiomer for anti-HBV activity did not begin until July of 1991 (FF 59), the anti-HBV activity of the enantiomer "would be fully expected" (Paper 88 at 23).

1. Conception

Furman's position is that "Drs. Painter and Furman had formulated the concept of the invention of the interference Count when they clearly indicated in their July 17, 1990 notebook entry that the compounds received from Dr. Liotta should be tested for anti-HBV activity." For reasons set forth below, we need not and do not decide whether we agree with Furman's position. Nonetheless, we note the following problems with Furman's position:

(1) It is not evident from the evidence presented whether the Furman inventors would have discussed sending the Liotta samples for anti-HBV testing (FF 33C) because they had a clear idea of using the samples in a method for treating HBV infection, because they were following the terms of the agreement with Emory (FF 30), or for some other reason.

The agreement with Emory University called for "anti-viral screening". (FF 30). It appears that there were four anti-viral screens in place[14] at BW during the relevant time frame (Paper 88 at 17). Dr. Painter's notebook indicates that the Liotta samples had already been sent for anti-HIV screening. Therefore, the anti-HBV screen was one of only three remaining anti-viral screens that could have been performed by BW pursuant to the agreement with Emory.

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[14] Evidence presented by Furman indicates the Dr. Korba's anti-HBV screen was not considered "in-house" at BW. (See, e.g., Exh. 2049 at ¶ 9). Nonetheless, evidence presented by Furman shows that Dr. Korba's anti-HBV screen was available to BW chemists during the relevant time frame. (Exh. 2017 and Exh. 2047).

(2) Evidence provided by Furman indicates that the Furman inventors did not know the structural identities of the Liotta samples at the time they were said to have discussed sending the samples for HBV testing. (FFs 24I, 24J and 33C). For conception to exist the inventors idea must include every feature of the claimed invention . *Coleman v. Dines*, 754 F.2d at 359, 224 USPQ at 862. For example, for conception of a chemical compound, the idea of the structure of the compound is required. *Oka v. Youssefyeh*, 849 F.2d 581, 583, 7 USPQ2d 1169, 1171 (Fed. Cir. 1988).

The 1989 discussion:

Furman has not argued or otherwise shown that the Furman inventors conceived the invention prior to July of 1990. For example, Furman does not contend that the Furman inventors conceived the invention in 1989 when, according to Dr. Furman's testimony, the Furman inventors discussed sending BCH-189 for anti-HBV testing ("the 1989 discussion"). (FF 24D). Even if Furman did rely upon Dr. Furman's testimony regarding the 1989 discussion for conception, Furman has not directed us to evidence that corroborates Dr. Furman's testimony regarding the discussion. An inventor must prove his conception by corroborating evidence, preferably by a showing of contemporaneous disclosure. *Burroughs Wellcome*, 40 F.3d at 1228, 32 USPQ2d at 1919.

Dr. Korba's testing:

Furman could argue that the Furman inventors conceived the invention based on the testing and results obtained by Dr. Korba. (FF 50-55). However, as discussed further *infra*, Furman has not shown that either of the Furman inventors himself requested anti-HBV testing of BCH-189 or that either of the Furman inventors ever learned of Dr. Korba's results.

Nonetheless, since Furman has not sufficiently shown a reduction to practice prior to Belleau's constructive reduction to practice on 3 January 1991, we need not and do not determine if Furman has shown that it conceived the invention of the counts prior to Belleau. Moreover, diligence is not an issue before us since Furman has not argued or otherwise shown that it was diligent up until its constructive reduction to practice date of 2 May 1991.

2. Reduction to practice

a. The July and August activity

Furman relies upon the doctrine of simultaneous conception and reduction to practice to establish that it reduced to practice an invention of the counts in July or August of 1990 (Paper 88 at 18). The doctrine of simultaneous conception and reduction to practice is somewhat rare, but certainly not unknown, especially in unpredictable arts such as chemistry and biology. *Mycogen Plant Science, Inc. v. Monsanto Co.*, 243 F.3d 1316, 1330, 58 USPQ2d 1030, 1041 (Fed. Cir. 2001). While Furman seems to be relying upon its conception to show a reduction to practice, our understanding is that the doctrine applies in the rare instance when a reduction to practice is required to establish conception. *See e.g., Amgen Inc. v. Chugai Pharma. Co.*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991).

Even if Furman has shown that its July and August activities establish conception,[15] we determine that Furman has not shown an actual reduction to practice based on these activities. In particular, Furman has not established that the Furman inventors had determined that BCH-189 worked for its intended purpose of treating HBV as of July or August of 2000.

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[15] As noted above, we have not decided if Furman has shown that it conceived the invention of the counts prior to Belleau.

Furman argues that Dr. Painter and Dr. Furman knew of the protein similarities of HIV and HBV and thus had a "reasonable assurance that BCH-189 would be useful in the treatment of HBV as well as HIV" (Paper 88 at 19). However, even if Furman has sufficiently established that Dr. Painter and Dr. Furman had a "reasonable assurance" that BCH-189 had anti-HBV activity, Furman has not sufficiently explained why only a reasonable assurance of efficacy is sufficient for a reduction to practice in the situation before us.

For instance, Furman has not argued that the invention of the counts is so simple that successful testing would not be required to establish a reduction to practice. *See Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1578, 38 USPQ3d 1288, 1291 (Fed. Cir. 1996) ("In fact, some inventions are so simple and their purpose and efficacy so obvious that their complete construction is sufficient to demonstrate workability"). Instead, Furman argues that (Paper 88 at 16):

> It is clear from Burroughs Wellcome [*Burroughs Wellcome Co. v. Barr Lab., Inc.*] that when inventors set out with a general goal of finding a method of treatment and the inventors had formulated the idea of the invention to the point that they express it clearly in written form, the invention has been reduced to practice even before testing proves their inventive concept to be correct.

Furman directs us to no particular portion of the *Burroughs Wellcome* decision. However, our understanding of the decision is not the same as Furman's. In particular, the *Burroughs* decision states that the fact that the inventors set out with the general goal of finding a method to treat AIDS and had formulated the idea of the invention to the point that they could express it clearly in the form of a draft patent application was evidence "that the idea was clearly

defined in the inventors' minds". However, the decision went on to state that the invention still needed to be reduced to practice through confirmation of its operability. *Burroughs Wellcome*, 40 F.3d at 1230, 32 USPQ2d at 1921.

b. The December activity

Furman argues that "as of December 12, 1990, there was convincing evidence that Drs. Painter's and Furman's earlier inventive concept and simultaneous reduction to practice was correct (Paper 88 at 22). It does not appear that Furman is arguing that the December activity itself amounted to an actual reduction to practice. Nonetheless, near the conclusion of its principal brief, Furman makes the statement that "[i]f December 12, 1990 is found to be the reduction to practice date", then Furman was diligent in obtaining Dr. Korba's test results (Paper 88 at 24).

Even if we were to construe Furman's statement as an argument that the December activity amounts to a reduction to practice rather than a confirmation of the earlier simultaneous conception and reduction to practice, the argument fails. For example, Furman does not explain how the December activity shows that the Furman inventors determined that the invention would work for its intended purpose. In particular, Furman has not directed us to evidence sufficiently establishing that the Furman inventors learned of Dr. Korba's results and thus determined that BCH-189 would work for its intended purpose.

Furman does not state that the Furman inventors tested BCH-189 and found it to have anti-HBV activity. Instead, Furman states that Dr. Korba tested BCH-189 and that his test results showed that BCH-189 had anti-HBV activity. Evidence presented by Furman indicates that the Furman inventors were on the distribution list for a BW memorandum that summarized Dr.

Korba's results. (FF 55). However, Furman has not directed us to evidence establishing that the Furman inventors actually received and read the memorandum.

Ms. Kondy testified that she or Dr. Biron would "sometimes" verbally communicate results to BW chemists. (FF 58). However, Furman has not argued or otherwise shown that Ms. Kondy's testimony establishes such a regular practice of verbal communication of results that we should infer that it more likely than not occurred on the occasion before us.

Furman has not shown that the Furman inventors themselves determined that the invention would work for its intended purpose. Furman has not presented us with an alternative theory as to why the December activity is a reduction to practice by the Furman inventors. In particular, Furman has not explained to us how the Furman inventors could have reduced to practice the invention of the count without actual knowledge of Dr. Korba's test results. For example, Furman does not argue that a reduction to practice occurred when Dr. Korba, Dr. Biron, or Ms. Kondy learned that BCH-189 exhibited anti-HBV activity in Dr. Korba's test.[16]

It is not our role to make out Furman's case for it nor would it be fair to Belleau for us to do so. *Leveen v. Edwards*, 57 USPQ2d at 1413 (BPAI (ITS) 2000) ("[t]he board will not engage in "role-shifting" by becoming counsel for a party and turning the interference into a contested case between (1) the party and the board, on the one hand, versus (2) the opponent, on the other hand").

Accordingly, we hold that Furman has not sufficiently shown a reduction to practice prior to Belleau.

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[16] Evidence submitted by Furman suggests that Dr. Korba did not know that one of the compounds he was testing, coded as DCL-12, was BCH-189. (Exh. 2052 at ¶ 7).

Inurement

As we note above, Furman does not argue that a reduction to practice occurred when Dr. Korba, Dr. Biron, or Ms. Kondy learned that BCH-189 exhibited anti-HBV activity in Dr. Korba's test. In particular, Furman does not argue that the acts of Dr. Korba, Dr. Biron, of Ms. Kondy inure to its benefit. Nonetheless, even if we were to consider the evidence pointed out to us by Furman, we would determine that Furman has not established inurement.

Inurement involves a claim by an inventor that, as a matter of law, the acts of another person should accrue to the benefit of the inventor. *Cooper v. Goldfarb*, 154 F.3d at 1331, 47 USPQ2d at 1904. There are at least three requirements that must be met before a non-inventor's recognition of the utility of an invention can inure to the benefit of the inventor. First, the inventor must have conceived the invention. Second, the inventor must have had an expectation that the embodiment tested would work for the intended purpose of the invention. Third, the inventor must have submitted the embodiment for testing for the intended purpose of the invention. *Genentech v. Chiron*, 220 F.3d 1345, 1354, 55 USPQ2d 1636, 1643 (Fed. Cir. 2000). An inventor must show that the other person was working, either explicitly or implicitly, at the inventor's request, but communication of the conception is not required. *Cooper v. Goldfarb*, 154 F.3d at 1332, 47 USPQ2d at 1905 (Fed. Cir. 1998).

As noted above, we make no determination of whether Furman has shown conception. However, Furman has not shown that Dr. Korba's testing and the results obtained from the testing inure to the benefit of Dr. Furman and Dr. Painter as Furman has not shown, inter alia, that:

(1) the Furman inventors had an expectation that BCH-189 would work for its intended purpose, and

(2) Dr. Korba tested BCH-189 for anti-HBV activity at the request of the Furman inventors.

We note the following portions of Dr. Furman's testimony:

(A) Dr. Furman's testimony that the Furman inventors, upon learning that BCH-189 had anti-HIV activity (in 1989), discussed sending BCH-189 to Dr. Korba for testing since "the compound could exhibit activity against hepatitis B". (FF 24D).

(B) Dr. Furman's testimony that once the Furman inventors learned that one of the Liotta samples was BCH-189 (in August of 1990), they discussed sending the sample that was BCH-189 to Dr. Korba for anti-HBV testing (FF 24M); and

(C) Dr. Furman's testimony that Dr. Biron sent BCH-189 to Dr. Korba for anti-HBV testing at the request of the Furman inventors. (FF 24N).

Dr. Furman's testimony indicates that, based on similarities in the active sites of the reverse transcriptase enzyme of HIV and the polymerase enzyme of HBV, the Furman inventors thought that BCH-189 "could" also have HBV activity. (FF 24C).

We are not sure that the Furman inventor's belief that BCH-189 "could" exhibit anti-HBV activity rises to the level of an *expectation* that BCH-189 would also have anti-HBV activity. Nonetheless, even if we determine that the above portions of Dr. Furman's testimony indicates such an expectation, Furman has not directed us to evidence corroborating these portions of Dr. Furman's testimony. As noted above, inventor testimony used to establish prior invention must be corroborated. We look to all the evidence pointed out to us by Furman,

including any circumstantial evidence of an independent nature, in accessing Dr. Furman's testimony.

Dr. Painter's notebook

While Furman has not submitted testimony from Dr. Painter, Furman has submitted what appear to be two of Dr. Painter's notebook entries. (FFs 31-37). The first witnessed notebook entry states that the samples had been sent for HIV screening and that the Furman inventors had discussed sending the Liotta samples "to Karen Biron HBV test" (FFs 33A-C). Both notebook entries are consistent with Dr. Furman's testimony that Dr. Liotta sent the Liotta samples for anti-viral testing and with the letters from Dr. Liotta requesting anti-viral testing of the samples. (FFs 26-29). Neither notebook entry explicitly states that the Furman inventors expected that any of the Liotta samples would be active against HBV or even HIV. Neither notebook entry indicates that either of the Furman inventors actually sent any Liotta sample for anti-HBV testing.

It seems reasonable that the Furman inventors could have discussed sending the Liotta samples for anti-HBV testing because there was an agreement between BW and Emory University to subject the samples to anti-viral screening. (FF 30).

It could be argued that the Furman inventors would have discussed sending the Liotta samples for anti-HBV testing because they had an expectation that the samples would be effective as anti-HBV treatments. However, Furman has not directed us to evidence sufficiently establishing a reason why the Furman inventors would have such an expectation. For example, the Furman inventors would not have expected the samples to have anti-HBV activity based on

their structure, since the identify of the Liotta samples was unknown to the Furman inventors at the time. (FFs 24I-L and 33A).

Ms. Kondy's testimony

Shelia (Smith) Kondy testified that she sent samples "from George Painter to Dr. Korba for HBV testing". Ms. Kondy's testimony does not say why she sent BCH-189 for the testing. For example, Ms. Kondy's testimony does not state that either of the Furman inventors asked her to send BCH-189 for anti-HBV testing.

We note that Ms. Kondy's notebook entry dated 31 October 1990 contains a notation "from G. Painter" under which are listed six compounds, one of which is BCH-189. (FF 47). Ms. Kondy's notebook entry is consistent with other evidence indicating that BCH-189 was received into BW by Dr. Painter (e.g., FFs 24I and 33A) and thus was "from G. Painter". However, the notebook entry is not sufficient to show that a Furman inventor explicitly asked Ms. Kondy to send BCH-189 for anti-HBV testing. Furman does not argue that and therefore we will not speculate as to whether Ms. Kondy sent BCH-189 to Dr. Korba at the implicit request of a Furman inventor.

Dr. Biron's testimony

Karen Biron testified that she would conduct a meeting to discuss "sample priority" since there were a limited number of samples that could be tested by Dr. Korba at any time. (FF 40). In her testimony, Dr. Biron refers to a memorandum dated 13 October 1989. (FF 41-42). The memorandum states that "[t]here will be a meeting to select the next ten compounds for testing against human HBV by Brent Korba of Georgetown". Neither Dr. Painter nor Dr. Furman is on the distribution list found at the bottom of the memorandum. It is not clear to us if the

memorandum is submitted as evidence to show that generally meetings were held to discuss what samples to send to Dr. Korba or as evidence to show that the Furman inventors were involved in the decision to send BCH-189 to Dr. Korba. At any rate, the memorandum does not show the latter since it does not mention either Furman inventor or the BCH-189 sample.

Dr. Biron's testimony does not indicate that a Furman inventor explicitly or implicitly requested that BCH-189 be sent for anti-HBV testing.

When we consider Dr. Furman's testimony in combination with other evidence pointed to by Furman, we determine that Furman has not shown that Dr. Korba's testing and test results, to the extent they can be said to be recognition of the utility of an invention, inured to the benefit of the Furman inventors. In particular, Furman has failed to show that the Furman inventors: (1) had an expectation that BCH-189 would work for its intended purpose, and
(2) requested anti-HBV testing of BCH-189.

In vitro testing

Furman has not shown that Dr. Korba's testing and results from the testing inure to the benefit of the Furman inventors. Accordingly, we need not and do not decide if Dr. Korba's test results amount to a determination that BCH-189 would work for its intended purpose. For example, we need not and do not decide if Dr. Korba's *in vitro* test was an adequate one given the scope of the interference counts, which at least include and are arguably limited to, *in vivo* utilities.

Diligence

Even if we determined that Furman's July, August, or December activities amounted to a conception, Furman has not argued[17] or otherwise shown that it was diligent up until 2 May 1991 (Furman's constructive reduction to practice date).[18]

The count 2 and count 3 compounds

Count 2 and count 3 are directed to a subset of the compounds defined by the count 1 where the compounds are either substantially free of the corresponding (+)-enantiomer (count 2 and count 3) or contain more of said (-)-enantiomer than the corresponding (+)-enantiomer (count 2).

Furman relies upon its argued reduction to practice of BCH-189 to show reduction to practice of the invention of counts 2 and 3. In particular, Furman argues that once BCH-189 was reduced to practice, the separate enantiomers were also reduced to practice since "once Dr. Korba proved that BCH-189 possessed anti-HBV activity, the anti-HBV activity of the BCH-189 enantiomers would be fully expected" (Paper 88 at 22-23). Furman has not shown a reduction to practice of the enantiomers of BCH-189 prior to Belleau for at least the same reasons that Furman had not shown a reduction to practice of BCH-189 prior to Belleau.

Moreover, even if Furman had shown a prior reduction to practice of BCH-189, Furman has not shown a prior reduction to practice of the compounds of count 2 or count 3. In particular,

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[17] Furman's only argument regarding diligence relates to Dr. Korba's testing which was said to have been performed diligently (Paper 85 at 19 and 21).

[18] We use 2 May 2001 as Furman's reduction to practice date for evaluating diligence since Furman has not established an earlier reduction to practice date on the record before us.

Furman has not shown that the Furman inventors determined that the compounds of count 2 or count 3 would work for their intended purpose. Furman concedes that the separate enantiomers of BCH-189 were not tested until July of 1991. (FF 59). Furman has not sufficiently explained why a reduction to practice of the count 2 and 3 compounds did not require successful testing.

We need not and do not determine whether the July 1991 testing itself amounted to a reduction to practice of a compound within the scope of count 2 or count 3 since the testing occurred after Furman's constructive reduction to practice date of 2 May 1991.[19]

IV. Conclusion

As junior party in the interference, Furman has the burden of proving priority by a preponderance of the evidence. 37 CFR § 1.657(b). Furman has not met its burden. Accordingly, we need not and do not consider Belleau's principal brief on the issue of priority (Paper 90).

Furman has not sufficiently shown that it either (1) reduced the invention of the counts to practice prior to Belleau or (2) conceived the invention of the counts prior to Belleau and then exercised reasonable diligence in later reducing the invention to practice. Since Furman has not shown priority as to any count, we need not and do not decide whether the subject matter of either count 2 or count 3 is separately patentable from the subject matter of count 1.

Accordingly, it is appropriate to award priority against Furman as to count 1, count 2 and count 3.

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[19] For example, we need not and do not determine if the July 1991 testing actually showed activity for the (-) enantiomer of count 2 and count 3.

V. Order

Upon consideration of the record of the interference and for reasons given, it is

ORDERED that judgment on priority is awarded against PHILLIP A. FURMAN and GEORGE R. PAINTER, III as to count 1, count 2, and count 3;

FURTHER ORDERED that PHILLIP A. FURMAN and GEORGE R. PAINTER, III is not entitled to a patent containing claims 1-5 of application 07/775,187;

FURTHER ORDERED that a copy of this decision and a copy of the redeclaration of this interference (Paper 66) each be given a paper number and each be entered in the administrative records of Belleau's 5,532,346 patent, Belleau's 09/585,431 application, and Furman's 07/775,187 application; and

FURTHER ORDERED that if there is a settlement agreement in the interference, the parties are directed to 35 USC § 135(c) and 37 CFR § 1.666.

RICHARD TORCZON
Administrative Patent Judge

SALLY GARDNER LANE
Administrative Patent Judge

MICHAEL P. TIERNEY
Administrative Patent Judge

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) APPEALS AND
) INTERFERENCES

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